

**Notice of Allowability**Application No.  
09/519,283

Applicant(s)

Bandman et al.

Examiner

Christian L. Fronda

Art Unit

1652

**-The MAILING DATE of this communication appears on the cover sheet with the correspondence address-**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Supplementary Amendment dated 4/4/2003 (Paper No. 25).
2. ☒ The allowed claim(s) is/are 21-25, 27, 29, 31-33, 45, and 46.
3. ☒ The drawings filed on Mar 7, 2000 are accepted by the Examiner.
4. ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \*Certified copies not received: \_\_\_\_\_

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.  
 (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.  
 (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.  
 (c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____             |
| 5 <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449), Paper No(s). _____          | 6 <input type="checkbox"/> Examiner's Amendment/Comment                             |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 9 <input type="checkbox"/> Other   |   |

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### EXAMINER'S AMENDMENT

1. Claims 21-25, 27, 29, 31-33, 45, and 46 are under consideration in this Office Action.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.  
Authorization for this examiner's amendment was given in a telephone interview with Shirley A. Recipon on April 29, 2003.
3. The application has been amended as follows:
  - In claim 21, line 4, delete the phrase "a naturally occurring", and replace with "an".
  - In claim 29, line 4, delete the phrase "naturally occurring".
  - In claim 31, line 7, delete the phrase "or fragments thereof".
  - In claim 33, line 3, delete the phrase "or fragment thereof".
  - In claim 33, lines 5-6, delete the phrase "or fragment thereof,".
  - In claim 45, line 4, delete the word "exposing" and replace with the word "contacting".
  - In claim 45, line 4, delete the word "to" and replace with the word "with".
  - In claim 46, line 1 delete the word "assessing" and replace with the phrase "screening for potential".
  - In claim 46, line 7, delete the phrase "or fragment thereof".
  - In claim 46, line 11, delete the phrase "is indicative of" and replace with the phrase "indicates potential".

### *Allowable Subject Matter*

4. Claims 21-25, 27, 29, 31-33, 45, and 46 are allowed.

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5. The following is an examiner's statement of reasons for allowance:

The prior art neither teaches nor suggests an isolated polynucleotide encoding a cathepsin having cysteine protease activity comprising an amino acid sequence having at least 90% identity to the amino acid sequence SEQ ID NO:1, amino acid sequence SEQ ID NO:1, or a proteolytically active fragment of the amino acid sequence of SEQ ID NO: 1.

The restriction requirement for claims 31-33 under 35 U.S.C. 121 set forth in the Office Action dated 10/03/2000 (Paper No. 6) has been withdrawn. Claims 21-29 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 45 and 46, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claim 45 and 46 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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**ALLOWED CLAIMS****Product claim 29 and Method Claims 31-33**

29. An isolated polynucleotide comprising a polynucleotide sequence encoding a cathepsin having cysteine protease activity selected from the group consisting of:

- a) a polynucleotide sequence of SEQ ID NO:2,
- b) a polynucleotide sequence having at least 90% sequence identity to the polynucleotide sequence of SEQ ID NO:2,
- c) a polynucleotide sequence complementary to a),
- d) a polynucleotide sequence complementary to b), and
- e) an RNA equivalent of a)-d).

31. A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 29, the method comprising:

- a) hybridizing the sample with a probe comprising at least 20 contiguous nucleotides comprising a sequence complementary to said target polynucleotide in the sample, and which probe specifically hybridizes to said target polynucleotide, under conditions whereby a hybridization complex is formed between said probe and said target polynucleotide, and
- b) detecting the presence or absence of said hybridization complex, and, optionally, if present, the amount thereof.

32. A method of claim 31, wherein the probe comprises at least 60 contiguous nucleotides.

33. A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 29, the method comprising:

- a) amplifying said target polynucleotide using polymerase chain reaction amplification, and
- b) detecting the presence or absence of said amplified target polynucleotide, and, optionally, if present, the amount thereof.